

**REMARKS**

Claims 30-50 have been canceled without prejudice. Claims 51-105 are newly added and are supported throughout the disclosure; particularly as follows: claims 51-64 find support in the originally filed claims and in the Examples, present in the specification, which demonstrate that the applicant had possession of an invention that could produce microencapsulated particles without the necessity of a classification step being performed during the microencapsulation process; claims 65-79 find support in the originally filed claims and in the specification at page 7, claims 80-93 find support in the originally filed claims and in the Examples present in the specification, and claims 94-105 find support in the originally filed claims and in the specification at pages 6 and 8, and in the Examples present in the specification. No new matter has been added.

Applicant thanks the Office for the courtesies extended to the Applicant's representative during the telephonic Examiner Interview on February 13. During this Interview, U.S. Patent 5,849,240 ("Miller") was discussed, together with several claims that Applicant asserts are distinguishable over Miller. The Examiner agreed to take the arguments presented by Applicant's representative under advisement.

**Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 30-39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant traverses this rejection. Applicant points out that the rejection of these claims is moot due to the cancellation of these claims. Accordingly, Applicant requests the withdrawal of this rejection.

Claims 30-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office argues that the use of the term "about" render these claims vague and indefinite. (OA at 3.) The rejection as applied to claims 30-50 is moot due to their cancellation. However, Applicant traverses this rejection against the possibility that it might be applied to the currently pending claims.

Use of the term "about" has been well recognized in patent prosecution for decades. The Office provides no statutory or case law authority for the proposition that the use of "about" is no longer acceptable in drafting of patent claims. In the absence of such support, and in the presence of substantial precedent, the Office has failed to make a prima facie case of indefiniteness. Applicant therefore requests the withdrawal of this rejection to the extent that it might be applied to the currently pending claims.

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**Rejections under 35 U.S.C. § 103(a)**

Claims 1-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Miller for obviousness. Applicant notes that the rejection of these claims is moot as claims 1-27 have been cancelled. However, Applicant traverses this rejection against the possibility that it might be applied to the currently pending claims.

Claims 51-64 are distinguishable over Miller on a variety of grounds. In particular, Miller requires that a classification step is performed during the microencapsulation process. (Miller at col. 1, lines 61-62, col. 4, lines 1-29.) In contrast, independent claim 51 requires that that no classification step is performed during the microencapsulation process. Accordingly, Miller fails to teach or suggest all of the claim limitations; Miller therefore cannot render claims 51-64 unpatentable for obviousness. MPEP § 2143.03. As noted above, Applicant was in possession of the claimed invention as evidenced by the Examples, present in the specification, which demonstrate that the applicant had possession of an invention that could produce microencapsulated particles without the necessity of a classification step being performed during the microencapsulation process. These Examples represent a description of a reduction to practice, which is sufficient to show possession. MPEP § 2163.02. Possession of the claimed invention as of the filing date sought is sufficient to find adequate written description of the invention. MPEP § 2163. For all of these reasons, Applicant asserts that claims 51-64 are patentable over Miller.

Claims 65-79 are distinguishable over Miller on a variety of grounds. In particular, Miller fails to teach or suggest simultaneously fluidizing and mixing the core material and the oil until microencapsulated particles are formed that comprise the core material and the oil, as is required by independent claim 65, and the claims that depend from it. Accordingly, Miller fails to teach or suggest all of the claim limitations. Miller therefore cannot render claims 65-79 unpatentable for obviousness. MPEP § 2143.03. For all of these reasons, Applicant asserts that claims 65-79 are patentable over Miller.

Claims 80-93 are distinguishable over Miller on a variety of grounds. In particular, Miller fails to teach or suggest mixing the core material and the oil, at a mixer work input ranging from 600 RPM to 2000 RPM, until microencapsulated particles are formed that comprise the core material and the oil. In fact, Miller teaches away from this mixer work input range throughout the disclosure of Miller and in particular at column 6, lines 35-38, and col. 11, lines 47-48 (Applicant notes that the disclosed chopping rate of 1500 RPM is NOT the same as the mixing rate of Miller, which is disclosed as being 350 RPM). Teaching away from a claimed invention mitigates against a finding of obviousness. MPEP § 2145.

Further, adjustment of the mixer work input rate would not be an instance of "routine experimentation." In fact, Miller provides no motivation whatsoever to vary the mixer work input to optimize any particular results-effective variable. For instance, Miller fails to teach or disclose that the mixer work input rate is a results-effective variable for achieving a recognized result: namely an embodiment of a microencapsulation process that does not require further classification. As noted above and set forth in the Examples, practice of the invention, including operation at the claimed mixer work input ranges, may result in a microencapsulation process that does not require a classification step, as required by Miller. Absent the recognition that mixer work input was a results-effective variable, for example to achieve an embodiment of a microencapsulation process that does not require further classification, one of ordinary skill in the art would have no motivation to vary the mixer work input of Miller to fall within the claimed range. Accordingly, Miller fails to teach or suggest all of the claim limitations. Miller therefore cannot render claims 80-93 unpatentable for obviousness. MPEP § 2143.03. For all of these reasons, Applicant asserts that claims 80-93 are patentable over Miller.

Claims 94-105 are distinguishable over Miller on a variety of grounds. In particular, Miller fails to teach or suggest an animal or vegetable oil with a melting point above about 110 Deg. F. and a maximum iodine value of 5.0, as required by independent claim 94, and the claims that depend from it. As noted in Attachment 1, Iodine Value is a measure of the degree of unsaturation of a fat or oil. As Iodine Value increases, the oxidative stability decreases. Accordingly, animal or vegetable oils that have Iodine Values greater than 5.0 will have decreased oxidative stability compared to the claimed invention, therefore affecting the oxidative stability and shelf life of pharmaceutical compositions that comprise such animal or vegetable oils.

Miller fails to teach or suggest all of the claim limitations. Miller therefore cannot render claims 94-105 unpatentable for obviousness. MPEP § 2143.03. For all of these reasons, Applicant asserts that claims 94-105 are patentable over Miller.

**CONCLUSION**


It is submitted that the present application is in form for allowance, and such action is respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 18284-703). A duplicate copy of this paper is enclosed.

Respectfully submitted,

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**Attachment 1**

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AMENDMENT OR RESPONSE TO OFFICE ACTION - PAGE 13 -

## FREE FATTY ACIDS (FFA)

Fatty acids that have broken free from the glycerin backbone of a glyceride due to oxidative pressure. The upper limit for FFAs in fresh oil is typically 0.05%.

## GAS CHROMATOGRAPHY (GC)

A process utilized to determine the fatty acid content of a triglyceride. Fat samples are vaporized at high temperatures separating the fatty acids and allowing for accurate determination of composition.

## GUMMING

Formation and accumulation of a fat insoluble sticky material resulting from continued heating of fats and oils. The gummy material is produced by oxidation and polymerization of the fat and represents fat breakdown products, which collect on heating surfaces.

## HARD BUTTER

A generic term used in the confectionery, biscuit and cracker, and vegetable dairy industries to describe a class of specialty fats with physical characteristics similar to those found in cocoa butter or dairy butter. These fats are used in formulating many food products whose performance depends in large part upon the properties of the fats they contain. Applications include confectionary coating and centers, as well as, imitation dairy products such as whipped toppings, coffee whiteners, imitation cheeses and margarines.

## HYDROGENATION

Hydrogenation is a process employed to increase the oxidative stability of a fat and/or modify its physical and functional properties. More specifically, hydrogenation results in higher melting points, higher solid fat contents, and longer shelf life without rancidity. The process of hydrogenation is performed under high temperature and pressure in the presence of a catalyst and involves the addition of hydrogen atoms to the carbon-to-carbon double bonds found in unsaturated fatty acids.

## HYDROLYSIS

A chemical reaction involving molecular breakdown by reaction with water. An "ester" may react or hydrolyze in the presence of water to form an acid and an alcohol. A fat or oil (special type of ester) yields free fatty acid and glycerin.

The modification process permits the random rearrangement of the fatty acids in the triglyceride molecules with respect to the 1, 2 and 3 positions of the glycerol moiety. The arrangement of fatty acids in any naturally occurring oil is usually in a specific pattern characteristic of that oil, but can be changed to a random arrangement with the aid of a catalyst. The interesterification process does not change the degree of unsaturation or isomerization.

## INTERESTERIFICATION

This process is widely used in the manufacture of lauric specialty fats. By combining hydrogenation and interesterification processes, solid fat content may be maintained at ambient temperatures while the melting point is significantly reduced. By employing a variety of oil blends, a wide range of solid fat profiles and melting ranges are achievable. Generally, these products are made from Palm Kernel and/or Coconut Oils in combination with lesser amounts of non-lauric fats such as Palm or Cottonseed.

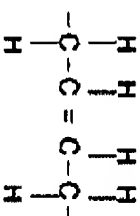
The Iodine Value is an expression of the degree of unsaturation of a fat. Measured by determining the amount of iodine, which will react with a natural or processed fat under prescribed conditions. The iodine reacts with the unsaturated groups (double bonds). Unsaturation is reduced and I.V. is lowered by hydrogenation while oxidative stability increases. The iodine value test is used only in the laboratory. Commercial fats do not contain iodine.

## IODINE VALUE (IV)

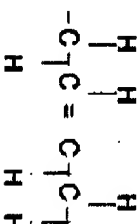
Isoomers are compounds which can exist in more than one form, although they contain the same elements in the same proportions. There are two important types of isomerism: (1) geometric and (2) positional.

Geometric Isomerism. Unsaturated fatty acids can exist in either the cis or trans form depending on where the hydrogen atoms are attached to the carbon backbone next to double bonds. If the hydrogen atoms on each side of the double bonds are on the same side, the arrangement is called cis. If these hydrogen atoms are on opposite sides, then the arrangement is called trans.

## ISOMERISM OF UNSATURATED FATTY ACIDS



cis



trans